

REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart H: Photon Emitting Remote Afterloader, Teletherapy, and Gamma Stereotactic Radiosurgery Units

- Deleted old §35.643, Modification of teletherapy unit or room before beginning a treatment program
 - ▶ This change will give licensees the flexibility in designing a radiation protection program that is specific to its facility and which assures that the dose limits in Part 20 are not exceeded

- Deleted old §35.645, Reports of teletherapy surveys, checks, tests, and measurements
 - ▶ The survey results are maintained by a licensee to show compliance with Part 20, and are available for review during inspections

§35.600 Use of sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit

- A licensee shall use sealed sources from these units for therapeutic medical uses:
 - ▶ As approved in the Sealed Source & Device Registry; or
 - ▶ In research in accordance with an active Investigational Device Exemption (IDE) application accepted by FDA
- Deleted references to specific radionuclides & devices uses

§35.604 Survey of patients and human research subjects treated with a remote afterloader unit

- Requires a radiation survey of a patient and the unit to confirm that the sources have been removed from the individual and returned to a shielded position before releasing the individual from licensee control
 - ▶ Note: This new requirement was previously imposed on remote afterloader licensees by a license condition
 - ▶ Note: For fractionated low or pulsed dose-rate treatments where the patient is not releasable under §35.75, surveys need only be performed after the last time the source is returned to the shielded position

§35.605 Installation, maintenance, adjustment, and repair

- Only a person specifically licensed by NRC or AS can install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit
- Except for low dose-rate remote afterloader units, only a person specifically licensed by NRC or an AS shall install, replace, relocate, or remove a sealed source or source contained in a device
- For low dose-rate remote afterloader units, an AMP is also allowed to install, replace, relocate, or remove a sealed source(s) contained in the unit

§35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

- Requires to secure the unit, console, console keys, and treatment room when not in use or unattended
 - ▶ Note: After 10/24 will no longer be a license condition for afterloaders due to codification
- Permit only approved individuals into the treatment room during treatment
- Prevent dual operation of radiation producing devices
 - ▶ Note: After 10/24 will no longer be a license condition for afterloaders due to codification
- Develop, implement, and maintain written emergency response procedures
 - ▶ Note: After 10/24 will no longer be a license condition due to codification

§35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (cont.)

- Copy of the licensee's written emergency response procedures must be physically located at the unit console
 - ▶ Note: In old rule, the procedures were required to be posted
- Location of emergency response procedures and telephone numbers must be posted at the unit console
- Licensee must provide initial and annual instruction in specifically identified procedures to all individuals who operate the device, and initial and annual practice drills in emergency procedures to operators, AMPs, and AUs

§35.615 Safety precautions

- Text was amended to include **remote afterloader units** and **gamma stereotactic radiosurgery units**
- Requirements to control access, and interlock system remain the same
- Individuals entering the treatment room **will use appropriate radiation monitors to check that radiation levels have returned to ambient levels**
- **Presence of AMP & AU during treatment was clarified**
- Deleted prescriptive requirements for beam condition indicator light and radiation monitor because they are addressed in Part 20

§35.615 Safety precautions (continuation)

- For medium & pulsed dose-rate remote afterloader units, the licensee shall require:
 - ▶ An AMP and either an AU or a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
 - ▶ An AMP and either an AU or an individual, under the supervision of an AU, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit
 - Note: Physically present means to be within hearing distance of normal voice. Immediately available means on-call basis (minimum, available by telephone)

§35.615 Safety precautions (continuation)

- For high dose-rate remote afterloader units, the licensee shall require:
 - ▶ An AU and an AMP to be physically present during the initiation of all patient treatments involving the unit; and
 - ▶ An AMP and either an AU or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit

- For gamma stereotactic radiosurgery units, the licensee shall require:
 - ▶ An AU and an AMP to be physically present throughout all patient treatments involving the unit

§35.615 Safety precautions (continuation)

- Requires to have emergency response equipment available near each treatment room to respond to a source:
 - ▶ Remaining in the unshielded position; and
 - ▶ Lodged within the patient following completion of the treatment
- Licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source
- Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient from the treatment console during irradiation
 - ▶ Note: The first two were license conditions - after 10/24 are codified

§35.630 Dosimetry equipment

- Most of the text remained unchanged except for the following revisions
- Requires that dosimetry systems be calibrated **using a source or system traceable to the NIST and in accordance with published protocols accepted by a nationally recognized body**; or by a calibration laboratory accredited by AAPM
 - ▶ Note: This change gives licensees two alternatives for direct traceability: either a source or the measurement instrument (well chamber) can be calibrated against a national standard
- Deleted the references to cobalt-60 and cesium-137 contained within teletherapy units

§35.630 Dosimetry equipment (continuation)

- Licensees using only low dose-rate remote afterloader units are not required to possess dosimetry equipment if they rely on the source output or activity determined by the manufacturer, as long as the manufacturer uses appropriately calibrated equipment and performs the calibration in accordance with published protocols accepted by a nationally recognized body
- Deleted the reference to intercomparison meetings sanctioned by a calibration laboratory or radiologic physics centers accredited by the AAPM

§35.632 Full calibration measurements on teletherapy units

- Almost all of the text remained unchanged except:
 - ▶ Deleted the reference to the AAPM Task Group Reports and replaced it with a requirement that **full calibration measurements be done in accordance with published protocols accepted by nationally recognized bodies**
 - ▶ Revised to include mathematical correction of output for physical decay for sources other than Co-60 (1 mo.) and Cs-137 (6 mo.): **all other nuclides (at intervals consistent with 1% physical decay)**
 - ▶ Full calibration measurements & physical decay corrections must be performed by an **AMP** instead of a “teletherapy physicist”

§35.633 Full calibration measurements on remote afterloader units

- Requirements are similar in content to §35.632, except:
 - ▶ Full calibration shall be done at intervals not exceeding 1 quarter for high/medium/pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and at intervals not exceeding 1 year for low dose-rate remote afterloader units
 - ▶ Full calibration must include, as applicable, determination of:
 - The output within +/- 5 percent;
 - Source positioning accuracy to within +/- 1 millimeter;
 - Source retraction with backup battery upon power failure;
 - Length of the source transfer tubes;
 - Timer accuracy and linearity over the typical range of use;
 - Length of the applicators; and
 - Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces

§35.633 Full calibration measurements on remote afterloader units (continuation)

- Calibration shall be made in accordance with published protocols accepted by nationally recognized bodies
- Licensee shall use the dosimetry system described in §35.630(a) to measure the output
- Additional requirement for low dose-rate remote afterloader units: Licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter
- For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer

§35.635 Full calibration measurements on gamma stereotactic radiosurgery units

- Requirements are similar in content to §35.632, except:
 - ▶ Full calibration shall be done at intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet
 - ▶ Full calibration must include, as applicable, determination of:
 - The output within +/- 3 percent;
 - Relative helmet factors & helmet microswitches;
 - Isocenter coincidence;
 - Timer accuracy and linearity over the range of use;
 - On-off error;
 - Trunnion centricity;
 - Treatment table retraction mechanism using battery or hydraulic backup;
 - Emergency timing circuits; and
 - Stereotactic frames and localizing devices (trunnions)

§35.635 Full calibration measurements on gamma stereotactic radiosurgery units (continuation)

- Full calibration shall be performed whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay
- A licensee shall use the dosimetry system described in §35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements may be made using a dosimetry system that indicates relative dose rates

§35.642 Periodic spot-checks for teletherapy units

- Requirements are similar in content to old §35.634, except:
- Monthly spot-checks & after each source installation
- "Beam condition indicator" replaced with term "source exposure indicator"
- Require an intercom system (this is a license condition)
- Deleted requirement to maintain a copy of the physicist's notification to the licensee of the spot-checks results

§35.643 Periodic spot-checks for remote afterloader units

- Requirements are similar to new §35.642, except A & B:
- A) Spot-checks are to be performed:
 - ▶ Before first use of a unit on a given day,
 - ▶ Before each patient treatment with a low dose-rate unit, and
 - ▶ After each source installation
- B) Assure proper operation of (these are some of them):
 - ▶ Viewing and intercom system in each remote afterloader facility
 - ▶ Emergency response equipment
 - ▶ Radiation monitors used to indicate the source position
 - ▶ Clock (time/date) in the unit's computer
 - ▶ Decayed source(s) activity in the unit's computer
- Lock the console (off position) & not use if a malfunction is identified except to repair, replace, or check system

§35.645 Periodic spot-checks for gamma stereotactic radiosurgery units

- Requirements similar in content to new §35.642, except:
- Spot-checks are to be performed:
 - ▶ Monthly,
 - ▶ Before first use of a unit on a given day, and
 - ▶ After each source installation
- A) For monthly spot-check assure proper operation of:
 - ▶ Treatment table retraction mechanism using backup system,
 - ▶ Helmet microswitches,
 - ▶ Emergency timing circuits, and
 - ▶ Stereotactic frames & localizing devices (trunnions)

§35.645 Periodic spot-checks for gamma stereotactic radiosurgery units (continuation)

- B) Also, for monthly spot-check must determine:
 - ▶ Output for one typical set of operating conditions,
 - ▶ Difference between measured and anticipated output,
 - ▶ Source output against computer calculation,
 - ▶ Timer accuracy & linearity over the range of use,
 - ▶ On-off error, and
 - ▶ Trunnion centricity

- A licensee shall arrange for the repair of any system identified in A & B that is not operating properly as soon as possible

§35.645 Periodic spot-checks for gamma stereotactic radiosurgery units (continuation)

- C) For spot-checks before first use each day, and after source installation, the licensee must assure proper operation of:
 - ▶ Electrical interlock at room entrance,
 - ▶ Source exposure indicator lights on unit, console, & facility,
 - ▶ Viewing and intercom system,
 - ▶ Timer termination,
 - ▶ Radiation monitors used to indicate room exposures, and
 - ▶ Emergency off buttons
- If the results required by C indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except to repair, replace, or check the system

§35.647 Additional technical requirements for mobile remote afterloader units

- Note: Requirements in this subsection were previously listed in "Supplement 1 to Policy & Guidance Directive FC 86-4; Revision 1, Mobile Remote Afterloading Brachytherapy Licensing Module"
- Licensee shall:
 - ▶ Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
 - ▶ Account for all sources before departure from an address of use

§35.647 Additional technical requirements for mobile remote afterloader units (continuation)

- In addition to periodic spot-checks as required by §35.643, a licensee shall perform checks on each unit before use at each address of use to verify the operation of:
 - ▶ Electrical interlocks on treatment area access points,
 - ▶ Source exposure indicator lights on unit, console, & facility,
 - ▶ Viewing and intercom system,
 - ▶ Applicators, source transfer tubes, and transfer tube-applicator interfaces
 - ▶ Radiation monitors used to indicate room exposures,
 - ▶ Source positioning (accuracy), and
 - ▶ Radiation monitors used to indicate whether the source has returned to a safe shielded position

§35.647 Additional technical requirements for mobile remote afterloader units (continuation)

- In addition to the requirements for checks in the last slide, a licensee shall ensure overall proper operation of the unit by conducting a simulated cycle of treatment before use at each address of use
- If the results of the checks indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system

§35.652 Radiation surveys

- In addition to the surveys required by §20.1501, a licensee shall perform surveys to ensure that the maximum and average radiation levels from the surface of the main source safe do not exceed the levels stated in the SSDR
- Surveys must be performed at installation of a new source and following repairs to:
 - ▶ The source(s) shielding,
 - ▶ The source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)

§35.655 Five-year inspection of teletherapy and gamma stereotactic radiosurgery units

- Units are to be inspected and serviced during source replacement, or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism
 - ▶ Note: Although most GSR licensees have license condition requiring inspection every 7 years; professionals in the medical community have indicated that the units are inspected on a more frequent basis
- Inspection and servicing may only be done by persons specifically licensed by NRC or Agreement States

§35.657 Therapy-related computer systems

- Licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with protocols accepted by recognized bodies

- Acceptance testing must include verification of:
 - ▶ Source-specific input parameters required by dose calculation algorithm;
 - ▶ Accuracy of dose, dwell time, & treatment time calculations at representative points;
 - ▶ Accuracy of isodose plots and graphic displays;
 - ▶ Accuracy of the software used to determine sealed source positions from radiographic images; and
 - ▶ Accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system

§35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

- Licensee shall require this AU to be a physician who:
 - ▶ 1) Is certified by a **medical specialty board**, or
 - ▶ 2) Has completed 200 hours of classroom & laboratory training, and 500 hours of work experience under the supervision of an AU who meets §35.690, or equivalent AS requirements, at a medical institution, and
 - ▶ Three years of supervised clinical experience in radiation oncology under the supervision of an AU who meets §35.690, and
 - ▶ **Has obtained a written certification by a preceptor AU who meets §35.690, or equivalent AS requirements**

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Subpart I: Reserved

Old Subpart I, “Teletherapy” was deleted

- **Subpart I: Reserved**

Deleted old Subpart I, “Teletherapy”